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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,050	10/30/2003	Orhan Soykan	P-10120.00	1185
7590 01/19/2006 Kenneth J. Collier Medtronic, Inc. 710 Medtronic Parkway N.E. Minneapolis, MN 55432			EXAMINER NATARAJAN, VIVEK	
			ART UNIT 3735	PAPER NUMBER

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/698,050		SOYKAN ET AL.	
	Examiner		Art Unit	
	Vivek Natarajan		3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/28/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 22-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/28/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Invention I, Claims 1-21 and 33-37 in the reply filed on 11/28/05 is acknowledged. The traversal is on the ground(s) that the elements of the independent claims are substantially similar and that two-way distinctness does not exist between the combination and subcombination. This is not found persuasive because the combination does not set forth the details of the subcombination as separately claimed, in particular the *plurality* of sensing elements anchored to a substrate. Furthermore, the subcombination has separate utility as an analyte measuring device used *outside* of the body and has practical applications that generally fall outside of the scope set forth in the combination.
2. The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

3. Claim 12 is objected to because of the following informalities: on line 3, the word "and" should be replaced by "or" so that the dye is only one of the chemical compounds on the list.
4. Claim 18 is objected to because of the following informalities: the claim recites "wherein **the a** light emitter...". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation “the energy is visible light”. It is unclear whether “the energy” refers to the illuminating energy, detected energy, or the energy exchanged between the dyes.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 11 recites “an analyte detector implanted in a body of the patient...”, which improperly includes a living subject as part of the claimed subject matter. The claim should be amended to recite “an analyte detector *adapted* to be implanted in...” to avoid this problem.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Chick et al. (US Patent No. 6,040,194).

9. Regarding Claims 1 and 4-7, Chick discloses a method for detecting an analyte in the human body comprising placing an analyte detector with two fluorescent dyes within the body, illuminating the detector, and measuring the analyte concentration based upon the ratio of energy emitted by the two dyes as a result of fluorescent resonant energy transfer (FRET) between them (col. 2, line 31 – col. 6, line 44).

10. Regarding Claims 2-3, a drug delivery system in communication with the analyte detector may be implanted in the body such that a feedback loop is established wherein a prescribed amount of drug is released when the measured analyte concentration exceeds a certain threshold (col. 6, lines 1-5).

11. Regarding Claim 8, the illuminating energy is visible light at a wavelength of 472 nm (col. 11, lines 36-47).

12. Regarding Claim 10, the analyte measured may be a narcotic such as cocaine or heroin (col. 5, lines 49-50).

13. Claims 1, 4-8, 11, 17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rao et al. (US Patent No. 5,628,310). Rao discloses a system for measuring *in vivo* analyte concentrations using FRET comprising a visible light emitter 4, analyte detector 6 (with two fluorescent dyes and a glucose binding protein), light detector 18, and processor 28 (col. 19, line 31 – col. 20, line 9).

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14. Regarding Claim 17, the system further comprises an alert module 32 to notify the patient based on the detection of a change in analyte concentration.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

16. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. as applied to Claim 1 above. Chick discloses a method for detecting an analyte in the human body comprising placing an analyte detector with two fluorescent dyes within the body, illuminating the detector, and measuring the analyte concentration based upon the ratio of energy emitted by the two dyes as a result of fluorescent resonant energy transfer (FRET) between them. Chick teaches that the system is suitable for measuring many different types of analytes, including antigens (col. 5, lines 31-32). Although Chick does not make explicit reference to the cardiac troponin-T antigen, official notice is taken that this particular protein is a well-known antigen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the system as disclosed by Chick et al. to measure cardiac troponin-

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T antigen concentrations, as this particular analyte is suitable for measurement with the system.

17. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al. as applied to Claim 11 above, and further in view of Kwon (Pub.No. US 2003/0113934). Rao discloses a system for measuring *in vivo* analyte concentrations using FRET comprising a light emitter 4, analyte detector 6 (with two fluorescent dyes and a glucose binding protein), light detector 18, and processor 28, but does not disclose the particular types of fluorescent dyes used. Kwon discloses a system for monitoring analyte concentrations in the body using FRET, wherein one of the dyes which may be used is tetramethylrhodamine isothiocyanate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use with the FRET system disclosed by Rao et al. the fluorescent dye tetramethylrhodamine isothiocyanate, since this dye allows for effective FRET analyte concentration measurements.

18. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al. as applied to Claim 11 above, and further in view of Chick et al. Rao discloses a system for measuring *in vivo* analyte concentrations using FRET comprising a light emitter 4, analyte detector 6 (with two fluorescent dyes and a glucose binding protein), light detector 18, and processor 28. Rao further indicates that the system may be in communication via a modem or antenna with an external diagnostic device (col. 1, lines 15-28), but does not explicitly disclose that the processor 28 compares the measured analyte concentration to a threshold and communicates the result to a

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therapy device. Chick discloses a FRET analyte monitoring system that communicates with a drug delivery device implanted in the body such that a feedback loop is established wherein a prescribed amount of drug is released when the measured analyte concentration exceeds a certain threshold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the analyte monitoring device as disclosed by Rao et al. in communication with a therapy device as taught by Chick et al. since this allows for a feedback loop to be established.

19. Claims 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al. in view of Chick et al. Rao discloses a system for measuring *in vivo* analyte concentrations using FRET comprising a light emitter 4, analyte detector 6 (with two fluorescent dyes and a glucose binding protein), light detector 18, and processor 28. Rao further indicates that the system may be in communication via a modem or antenna with an external diagnostic device (col. 1, lines 15-28), but does not explicitly disclose that the processor 28 compares the measured analyte concentration to a threshold and communicates the result to a therapy device. Chick discloses a FRET analyte monitoring system that communicates with a drug delivery implanted in the body such that a feedback loop is established wherein a prescribed amount of drug is released when the measured analyte concentration exceeds a certain threshold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the analyte monitoring device as disclosed by Rao et al. in communication with a therapy device as taught by Chick et al. since this allows for a feedback loop to be established.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Natarajan whose telephone number is (571)272-6249. The examiner can normally be reached on Mon-Fri, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on (571)272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VN

ERIC F. WINAKUR
PRIMARY EXAMINER